

NOV 14 1996

DeRoyal Industries, Inc.
Criss-Cross Vest Restraint

K963470

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME:	DeRoyal Industries, Inc.	TELEPHONE:	(423) 938-7828
ADDRESS:	200 DeBusk Lane	CONTACT:	Camille Matlock
	Powell, TN 37849	DATE OF PREPARATION:	August 30, 1996

DEVICE NAMES

NAME:	DeRoyal Industries, Inc. Criss-Cross Vest Restraint
COMMON/USUAL NAME:	Criss-Cross Vest Restraint
CLASSIFICATION NAME (if known):	Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETING DEVICES

J.T. Posey Company
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Criss-Cross Vest Restraint is a protective restraint device that is intended for medical purposes to limit patient movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Criss-Cross Vest Restraint is designed similar to those marketed by other manufacturers. The Criss-Cross Vest Restraint is primarily comprised of cool knit, cotton, or plaid tietex with polyester straps. The fasteners are made of a nylon hook and loop, plastic, or steel nickel plated buckles.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Criss-Cross Vest Restraint is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit patient movements thereby enabling examination or protection of the patient or others. The Criss-Cross Vest Restraint is a protective restraint that is intended to be used with a bed or wheelchair.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of plaid or white tietex, cotton flannel or polyester cool knit. The straps are made of polyester twill tape and white webbing. Fasteners are made of hook and loop, plastic, or steel nickel plated buckles.	Same
Size	Small, Medium, Large, X-Large, XX-Large	Same
Vehicles for Attachment	Bed or Wheelchair	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly agitated or disoriented Reminder	Same